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SANDOZ, INC.

PHARMACEUTICAL DIVISION
DRUG REGISTRATION &
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July 29, 1982

William Gyarfas, M.D., Director
Division of Oncology and Radio-
pharmaceutical Drug Products
Bureau of Drugs, HFD-150
Att: Document Control Room
17B-34
5600 Fishers Lane
Rockville, Maryland 20857

NDA #18-772
Sandimmune™(Cyclosporine)
Concentrate for Infusion
Original New Drug Application
NDA Sections 2&3, 10&16
FDA Classification: Category 1A

Dear Dr. Gyarfas:

In accordance with 21 CFR 314.1 and Section 505(b) of the Federal Food, Drug and Cosmetic Act, Sandoz Pharmaceuticals herewith submits, in triplicate, NDA Sections 2&3, 10 and 16 (i.e., nonclinical summary/full reports/literature and GLP Statement) for Sandimmune™(Cyclosporine) Concentrate for Infusion. By prior agreement, permission has been granted to file this new drug application sequentially.

NDA Sections 6,7,8,9 and 15 (i.e., manufacturing and controls data, environmental impact analysis report, drug samples) were submitted on April 22, 1982 at which time NDA number 18-772 was assigned. The remaining NDA clinical/ statistical/miscellaneous sections will be submitted in October 1982.

Sandoz, Inc., considers the information contained in this submission to be confidential.

Sincerely,

SANDOZ PHARMACEUTICALS

Richard J. Raffa
Senior Project Coordination
Manager

RJR:vb
Submitted in triplicate
Attachment: NDA Volumes 2.1-2.2 (inclusive)

cc: Mr. Stanley A. Stringer, Chief
Product Coordination Staff (HFD-105)

SANDOZ, INC.

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PHARMACEUTICAL DIVISION
DRUG REGISTRATION &
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July 29, 1982

William Gyarfas, M.D., Director
Division of Oncology and Radio-
pharmaceutical Drug Products
Bureau of Drugs, HFD-150
Att: Document Control Room
17B-34
5600 Fishers Lane
Rockville, Maryland 20857

NDA #18-773
Sandimmune™(Cyclosporine)
Oral Solution
Original New Drug Application
NDA Sections 2&3, 10&16
FDA Classification: Category 1A

Dear Dr. Gyarfas:

In accordance with 21 CFR 314.1 and Section 505(b) of the Federal Food, Drug and Cosmetic Act, Sandoz Pharmaceuticals herewith submits, in triplicate, NDA Sections 2&3, 10 and 16 (i.e., nonclinical summary/full reports/literature and GLP statement) for Sandimmune™(cyclosporine) Oral Solution. By prior agreement, permission has been granted to file this new drug application sequentially.

NDA Sections 6,7,8,9 and 15 (i.e., manufacturing and controls data, environmental impact analysis report, drug samples) were submitted on April 22, 1982 at which time NDA number 18-773 was assigned. The remaining NDA clinical/ statistical/miscellaneous sections will be submitted in October 1982.

Sandoz, Inc., considers the information contained in this submission to be confidential.

Sincerely,

SANDOZ PHARMACEUTICALS

Richard J. Raffa
Senior Project Coordination
Manager

RJR:vb
Submitted in triplicate
Attachment: NDA Volumes 2.1-2.17 (inclusive)

cc: Mr. Stanley A. Stringer, Chief
Product Coordination Staff (HFD-105)